510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 576-3544 Contact person: Kay A. Taylor Date prepared: August 17, 2000
Predicate device	The Tina-quant® Rheumatoid Factors II Test System is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Cobas® Integra Reagent Cassette for Rheumatoid Factor II (K000534).
Device name	**Proprietary name**: Tina-quant® Rheumatoid Factors II Test System **Common name**: Rheumatoid Factor Immunoassay **Classification name**: System, Test, Rheumatoid Factor
Device description	The device is a particle enhanced immunoturbidimetric test where antigen/antibody complexes form which are measured turbidmetrically.

510(k) Summary, continued

Intended use

For the quantitative immunological determination of human rheumatoid factors in serum and plasma.

Indication for use

Rheumatoid factor measurements may be used as an aid in the diagnosis of rheumatoid arthritis.

Substantial equivalence

The Tina-quant Rheumatoid Factors II Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the Cobas® Integra Reagent Cassette for Rheumatoid Factor II (K000354).

Substantial equivalence – similarities

The following table compares the Tina-quant Rheumatoid Factors II Test System with the predicate device.

Feature	Tina-quant® Rheumatoid Factors II Test System	Predicate Device
Intended use	For the quantitative immunological determination of human rheumatoid factors.	For the quantitative immunological determination of human rheumatoid factors.
Indication for use	An aid in the diagnosis of rheumatoid arthritis	An aid in the diagnosis of rheumatoid arthritis
Sample Type	Serum & plasma	Serum & plasma
Methodology	Immunoturbidimetric	Immunoturbidimetric
Calibration frequency	• Each lot • Per QC procedures	• Each lot • After 180 days
Storage & Stability	On board in use = 90 days	On board in use at 8°C = 8 weeks
Measuring range	• 0-120 IU/ml • with post-dilution 0-600 IU/ml	• 0-120 IU/ml • with post-dilution 0-600 IU/ml
Sample tubes	Na_2-EDTA, K_2-EDTA, K_3-EDTA, Li-Heparin, Na-Heparin.	Na_2-EDTA, K_2-EDTA, Li-Heparin, Na-Heparin, Na-Citrate.
Calibrator	Preciset RF	Preciset RF

510(k) Summary, continued

Substantial equivalence – differences

The following table compares the Tina-quant® Rheumatoid Factors II Test System with the predicate device.

Feature	Tina-quant® Rheumatoid Factors II Test System	Predicate Device
Instrument	Hitachi 917	Integra 400 & 700
Wavelength	570nm	583nm
Traceability / Standardization	WHO Standard 64/2.	World Health Organization Reference Preparation for Rheumatoid Factors (1st preparation, 1970)
Prozone Effect	> 6000 IU/ml	> 10,800 IU/ml
Control	RF Control Set	RF/ASO T Control II

510(k) Summary, continued

Substantial equivalence – performance characteristics

The Performance characteristics of the Tina-quant® Rheumatoid Factors II Test System and the predicate device are compared in the table below.

Feature	Tina-quant® Rheumatoid Factors II Test System	Predicate Device
Within-run precision (%CV)	Controls: 1.44% at 17.2 IU/ml 0.52% at 39.6 IU/ml Serum: 1.60% at 16.1 IU/ml 0.40% at 70.3 IU/ml	Controls: 1.1% at 51 IU/ml 1.0% at 80 IU/ml
Total precision (%CV)	Controls: 4.25% at 17.7 IU/ml 2.93% at 40.4 IU/ml Serum: 3.99% at 16.3 IU/ml 2.59% at 38.0 IU/ml	Controls: 6.8% at 51 IU/ml 4.4% at 80 IU/ml
Detection limit	2.4 IU/ml	1.25 IU/ ml
Limitations	• Icterus- No significant interference up to an I index of 60. • Hemolysis- No significant interference up to an H index of 1000. • Lipemia (Intralipid)- No significant interference up to an L index of 500.	• Hemolysis – no significant interference • Icterus - no significant interference • Lipemia - no significant interference • Pathologically high levels of γ-globulin (25 g/L) decrease the apparent RF concentration
Method Comparison - Passing-Bablok Correlation	Hitachi 917 RF II / Integra 700 RF II Y= 0.946X – 0.956 IU/ml	Integra 700 RF II / Integra 700 RF Y=0.89X + 8 IU/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 5 2000

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K002609
Trade Name: Tina-quant® Rheumatoid Factors II Test System
Regulatory Class: II
Product Code: DHR
Dated: August 17, 2000
Received: August 22, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K002609

Device Name: Tina-quant® Rheumatoid Factor II Test System

Indications For Use:

For the quantitative in vitro determination of rheumatoid factors in human serum and plasma on automated clinical chemistry analyzers. Rheumatoid factor measurements may be used as an aid in the diagnosis of rheumatoid arthritis.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Paul E. Makris

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002609